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10/804,381	03/19/2004	Scott Edward Osborne	7892C	7237

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EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/804,381  
Filing Date: March 19, 2004  
Appellant(s): OSBORNE ET AL.

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Roddy Bullock  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5-16-07 appealing from the Office action  
mailed 12-20-06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

A statement that there are no related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal, is present in the brief.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

With respect to the double patenting rejection, applicants have agreed to file a terminal disclaimer upon indicating allowable subject matter. Since no claims were allowed, the double patenting rejection has been maintained.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,643,588 to Roe in view of US 6,562,802 to Johansson et al.

Roe teaches a diaper (reads on the instant article), comprising a lotioned topsheet, wherein the lotion composition is a semisolid or a solid at 20degrees C and is adapted to be transferred to the wearer's skin (as claimed, col. 9-10). The lotion of Roe comprises emollients (read on claimed protectants) such as petrolatum, fatty acid ester, fatty alcohols, polysiloxanes, waxes etc (col. 11-12); immobilizing agents (cols. 13-16), surfactants (col. 16-18), including those having HLB value in the claimed range. For paraffin wax, see example 6 and claim 19. Roe further teaches incorporating active agents such as pharmaceutical or antibacterial active agents in the lotion, particularly therapeutic agents (Col.18). Roe fails to teach the claimed chitosan.

Johansson teaches topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). The components urea, lactic acid, paraffin liquid and polyoxyethylene-2-stearyl-ether read on the claimed skin protectant, pH control agent, and barrier protectant and

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release agent respectively. Johansson teaches skin composition containing chitosan in the form of cream, lotion or gel and suggests the addition of an amine- containing polymer, chitosan, for successful binding of antiallergenic substances such as EDTA (meets limitation of claim 4)(col. 8). Johansson teaches that the chitosan polymer forms a barrier protection and prevents contact of skin with the allergens or other irritants.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add chitosan and anti-allergens such as EDTA of Johansson to the lotion composition applied to a diaper (of Roe) because Johansson suggests that chitosan has superior features to make it a skin or mucus membrane protector when combined with an anti-allergen and is very effective in protecting skin during therapeutic treatments with anti-viral, anti-bacterial treatment or for UV protection (col. 6 and 8).

Roe and Johansson suggest various percentages or amounts of the claimed components that fall within the claimed ranges and accordingly, optimizing the amounts of the same so as to achieve the optimum release of the active agent to skin and at the same time provide barrier protection to skin from irritants or allergens would have been within the scope of a skilled artisan.

#### **(10) Response to Argument**

Applicants argue that there is no motivation to combine the cited references to achieve the lotion of Roe having chitosan as a skin care active (as claimed in claims 1-9 and 11-19). It is argued that the difference between the claimed invention and the prior art is the presence of chitosan as a skin care active in a lotion, which also has a skin

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protector (barrier protectant), which is paraffin wax. It is argued that the claimed invention has nothing to do with chitosan being used a skin protector. It is argued that Johansson fails to teach chitosan as a skin care active and that there is no motivation to include the additional skin protector of Johansson in the lotion of Roe, which already has a skin protector. Applicants' arguments are not persuasive because instant claims recite skin care active, without specifying the type of care or activity imparted by chitosan. Further, Johansson teaches that chitosan is active against protecting the skin from irritating agents, which in other words provides care to skin and hence reads on the instant skin care active. Johansson also teaches chitosan as preventing skin irritation by forming a buffering layer on the skin and has a high capacity to neutralize against acid and alkaline materials (col. 16, L 35-52) and thus the chitosan (of Johansson) not only provides protection but also provides skin care by preventing irritation to skin. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to combine two different substances recognized for the same activity (skin protecting) with an expectation to achieve improved or enhanced activity (skin protection). Applicants argue that page 7 of the instant specification describes a skin protectant as an "optional" skin care active and that the skin care active cannot be a skin protector in a claimed invention because there is already a skin protectant claimed. It is argued that a skin care active must be something other than a skin protectant. Applicants' arguments are not persuasive because neither instant claims nor the instant specification describe such limitations.

It is argued that the mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination. It is argued that in the cited combination is purely the result of inexpressible hindsight to pick and choose ingredients from disparate references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, both Roe and Johansson teach lotions containing skin-protecting agents, thus constituting analogous art and provide the requisite motivation to combine the teachings. While paraffin wax of Roe protects skin by forming a barrier protection and thus reduces the affinity of the bowel material to skin, the skin protecting chitosan forms a barrier and prevents any irritation to skin.

With respect to the argument that Johansson fails to teach the dispensing means and the method of application (claims 14-19), Roe clearly teaches the claimed dispensing means and also teaches addition of a lotion containing skin protecting agents. The teachings of Johansson have been cited for the claimed chitosan and not for dispensing means. Applicants argue that the cited references fail to suggest the claim limitations i.e., "method of applying" by a dispensing means and "exposing to

moisture" (claim 17). However, the method of applying a lotion containing a skin protecting substance such as paraffin wax is clearly taught by Roe. With respect to the argument regarding "exposing to moisture" of instant claim 17, claim 17 recites the steps of

- (a) applying to the skin an article comprising a dispensing means and a release composition disposed on at least a portion of the dispensing means;
- (b) transferring at least a portion of the release composition to the skin;
- (c) exposing the release composition to moisture and
- (d) releasing one or more skin care active ingredients from the release composition.

Roe teaches applying a lotion composition on a diaper, which is transferable to the wearer's skin and thus reads on the first two steps. With respect to "exposing to moisture", instant specification (on page 29) states that the composition is exposed to the moisture in the surroundings, which enhances the release and that no other intervention is required. The moisture in the surroundings can include the moisture from the skin of the wearer (of the article). Instant specification describes that the article may be an absorbent article such as for an infant use, which is also taught by Roe.

Therefore, it would have been obvious for a skilled artisan at the time for the instant invention that when an infant wears the diaper containing the lotion composition of Roe, the composition on the diaper is exposed to the same surroundings as that contemplated by the instant invention, for instance, moisture from the infant's skin or the



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moisture from the bowel materials. Thus, the prior art cited teaches the argued claim limitations.

Therefore, the rejection has been maintained.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Conferees:



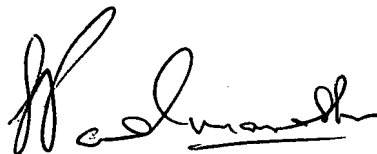
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